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09/884,244	06/19/2001	Simon John Mantell	PC10920A	3840

7590 06/02/2003

Paul H. Ginsburg
Pfizer Inc
20th Floor
235 East 42nd Street
New York, NY 10017-5755

EXAMINER

YOUNG, JOSEPHINE

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,244

Applicant(s)

MANTELL ET AL.

Examiner

Josephine Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26, 43-46 and 48-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26, 43-46 and 48-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 6.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in Paper No. 5, mailed March 25, 2003, is acknowledged. Further, Applicant's election of species, namely the compound of Example 1, N-({9-[(2R,3R,4S,5R)-3,4-dihydroxy-5-(hydroxymethyl)tetrahydro-2-furanyl]-6-[(2,2-diphenylethyl)amino]-9H-purin-2-yl)methyl)-N'-[2-(diisopropylamino)ethyl]urea, in Paper No. 5, mailed March 25, 2003, is acknowledged.

Amendments filed March 25, 2003

In the amendment filed March 25, 2003, claims 27-42 and 47 were cancelled. Claims 26 and 43-46 were amended. Claims 48-54 were added.

An action on the merits of claims 1-26, 43-46 and 48-54 is contained herein below.

Specification

The disclosure is objected to because of the following informalities: The specification, on page 122, lines 9-11, refers to methods to assess the biological activity of the compounds of the Examples on page 42. However, page 42 only contains a method for preparing a particular compound of the present invention.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims 1-26, 43-46 and 48-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 24, and 27 of U.S. Patent No. 6,326,359 to MONAGHAN et al. (A) in view of the article JACOBSON et al., J. Med. Chem., 1992, 35 (3), 407-422 (U). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentable distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Specifically, claim 1 of U.S. Patent No. 6,326,359 is directed to 5'-alkylated or cyclopropylmethylated adenosine derivatives, wherein A can be NR^a , $\text{NR}^a\text{C}(\text{O})$, $\text{NR}^a\text{C}(\text{O})\text{NR}^a$, or NR^aSO_2 ; and R^3 is $-(\text{CH}_2)_p\text{-R}^p\text{-B}$; such that $-\text{A-R}^3$ can be $-\text{NR}^a\text{C}(\text{O})\text{NR}^b\text{R}^b$, $-\text{NR}^a\text{SO}_2\text{NR}^b\text{R}^b$,

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or $-NR^aC(O)CONR^a(CH_2)_p-R^p-B$. Claims 24, and 27 of U.S. Patent No. 6,326,359 are directed to pharmaceutical compositions containing such compounds and processes for preparing such compounds, respectively.

Claims 1, 24, and 27 of U.S. Patent No. 6,326,359 do not recite the unprotected hydroxymethyl derivatives or the 5'-uronamide derivatives, pharmaceutical compositions containing such compounds or processes for preparing such compounds. Further, claims 1, 24, and 27 of U.S. Patent No. 6,326,359 do not recite compounds, compositions or processes for preparing compounds wherein Y is CS or C=N(CN). Finally, claims 1, 24, and 27 of U.S. Patent No. 6,326,359 may not recite each possible synthetic process to arrive at the compounds as defined by claim 1 of the present application.

JACOBSON teaches that the unprotected hydroxymethyl adenosine derivatives and 5'-uronamide adenosine derivatives are agonists of adenosine A2 receptors. See Table II, pages 410-411.

It would have been obvious to one of ordinary skill in the art to make and use the unprotected hydroxymethyl adenosine derivatives or the 5'-uronamide derivatives of the compounds of claims 1, 24, and 27 of U.S. Patent No. 6,326,359. A skilled artisan would have been motivated and had a reasonable expectation of success to use the unprotected hydroxymethyl adenosine derivatives or the 5'-uronamide derivatives to agonize adenosine A2 receptors, as JACOBSON teaches that such derivatives are also A2 receptor agonists. Further, it would have been obvious to one of ordinary skill in the art to make and use compounds wherein Y is CS or C=N(CN) as such derivatives are well known in the art to be functionally equivalent to CO and are considered well within the purview of the prior art. Finally, it would have been

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obvious to one of ordinary skill in the art to use any known synthetic method to couple amides or amide equivalents with amines to form ureas or urea derivatives as such synthetic manipulations are considered well within the purview of the prior art. Similarly, acylating and sulphonylating are processes well known in the art and considered a choice of experimental design well within the purview of the prior art.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-26, 44-46 and 48-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. This is a written description rejection.

A written description analysis involves three principle factors:

- (1) field of the invention and predictability of the art,
- (2) breadth of the claims, and
- (3) possession of the claimed invention at the time of filing for each claimed species/genus.

The breadth of the claim is such that compounds, and therefore the intermediates and processes for making and using such compounds, include 5'-uronamides of disubstituted amines. The specification presents a broad genus of compounds that purportedly are adenosine A2a receptor agonists. The specification states on page 31, lines 24-36, that the compounds of formula (I) are anti-inflammatories as demonstrated by their ability to inhibit neutrophil function, which indicates adenosine A2a receptor agonist activity. However, a statement of a potential effect does not constitute a sufficient written description for compounds that are 5'-uronamides of disubstituted amines; moreover, the support in the specification is not adequate for the claim to processes of using the 5'-uronamides of disubstituted amines for agonizing the adenosine A2a receptor or for the treatment of any disease.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by functional characteristics sufficient to show the Applicant was in possession of the claimed genus. There are a variety of congeners – 5'-hydroxy, 5'-uronamide of monosubstituted amines, 5'-uronamide of disubstituted amines, etc. - each with a certain degree of specificity for which there is not seen support for 5'-

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uronamide of disubstituted amines as agonists of the adenosine A2a receptor in the instant specification, the disclosed utility of the broad genus. There is limited predictability in the art that any one compound or class of compounds is capable of agonizing the adenosine A2a receptor. See for example the article OLSSON et al., J. Med. Chem., 1986, 29 (9), 1683-1689 (V). OLSSON teaches on page 1683, left column, last sentence, that uronamides of dialkylamines are inactive. To provide adequate support for the breadth of the claims, Applicant would have to establish that this class of compounds would also be effective in agonizing the adenosine A2a receptor, the disclosed utility of the present invention. The specification teaches the efficacy of 5'-uronamides of monosubstituted amines; however, this does not correlate to efficacy of 5'-uronamides of disubstituted amines as is broadly claimed. An adequate representation requires that the species that are expressly described be representative of the entire genus and what constitutes a "representative number" is an inverse function of the predictability of the art. As such, a skilled artisan would not recognize that a 5'-uronamides of monosubstituted amines would be representative in function to the genus of compounds as broadly claimed. As such, there is not seen any data that supports Applicant's claim that at the time of filing, the compounds of the invention were effective in agonizing the adenosine A2a receptor and inhibiting neutrophil function.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below in In re Wands USPQ2d 14000. A conclusion of lack of enablement means that, based on the evidence regarding a fair evaluation of an appropriate

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combination of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention.

These factors include

- (1) quantity of experimentation necessary,
- (2) the amount of guidance presented,
- (3) the presence or absence of working examples,
- (4) the nature of the invention,
- (5) the state of the prior art,
- (6) the predictability of the art and
- (7) the breath of the claims.

Claims 1-26, 44-46 and 48-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making and using 5'-uronamides of monosubstituted amines, does not reasonably provide enablement for making and using 5'-uronamides of disubstituted amines. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

With regard to factors (1) and (2) cited above, undue experimentation is required to determine how to synthesize the 5'-uronamides of disubstituted amines and which derivative would be efficacious for agonizing the adenosine A2a receptor for which the instant invention is applicable. There has not been provided adequate guidance in the written description for

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accomplishing such, as only the synthesis of 5'-uronamides of monosubstituted amines were described and no 5'-uronamides of disubstituted amine were assayed for its adenosine A2a receptor agonist activity.

With regard to factors (4), (5) and (6), it is noted that there is a great deal of unpredictability in the art. For example, as set forth supra, OLSEN teaches on page 1683, left column, last sentence, that uronamides of dialkylamines are inactive. The art at the time the invention was made fails to establish predictability with regard to the properties of the nucleosides and nucleotides analogs needed to perform the methods as instantly claimed.

With regard to factors (3) and (7), it is noted that while there are some working examples of 5'-uronamides of monosubstituted amines, it is not seen as sufficient to support the breadth of the claims. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves. See *In re Gardner et al.* 166 USPQ 138 (CCPA 1970).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-26, 43-46 and 48-54 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,326,359 to MONAGHAN et al. (A) in view of the article JACOBSON et al., J. Med. Chem., 1992, 35 (3), 407-422 (U).

As set forth supra, MONAGHAN teaches 5'-alkylated or cyclopropylmethylated adenosine derivatives, wherein A can be NR^a , $\text{NR}^a\text{C}(\text{O})$, $\text{NR}^a\text{C}(\text{O})\text{NR}^a$, or NR^aSO_2 ; and R^3 is $-(\text{CH}_2)_p\text{-R}^p\text{-B}$; such that $-\text{A-R}^3$ can be $-\text{NR}^a\text{C}(\text{O})\text{NR}^b\text{R}^b$, $-\text{NR}^a\text{SO}_2\text{NR}^b\text{R}^b$, or $-\text{NR}^a\text{C}(\text{O})\text{CONR}^a(\text{CH}_2)_p\text{-R}^p\text{-B}$. See claim 1. Further, MONAGHAN discloses pharmaceutical compositions containing such compounds and various processes for preparing such compounds, respectively.

MONAGHAN does not specifically teach the unprotected hydroxymethyl derivatives or the 5'-uronamide derivatives, pharmaceutical compositions containing such compounds or processes for preparing such compounds. Further, MONAGHAN does not explicitly teach compounds, compositions or processes for preparing compounds wherein Y is CS or $\text{C}=\text{N}(\text{CN})$. Finally, MONAGHAN may not teach each possible synthetic process to arrive at the compounds as defined by claim 1 of the present application.

JACOBSON teaches that the unprotected hydroxymethyl adenosine derivatives and 5'-uronamide adenosine derivatives are agonists of adenosine A2 receptors. See Table II, pages 410-411.

It would have been obvious to one of ordinary skill in the art to make and use the unprotected hydroxymethyl adenosine derivatives or the 5'-uronamide derivatives of the compounds of MONAGHAN. A skilled artisan would have been motivated and had a reasonable expectation of success to use the unprotected hydroxymethyl adenosine derivatives or

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the 5'-uronamide derivatives to agonize adenosine A2 receptors, as JACOBSON teaches that such derivatives are also A2 receptor agonists. Further, it would have been obvious to one of ordinary skill in the art to make and use compounds wherein Y is CS or C=N(CN) as such derivatives are well known in the art to be functionally equivalent to CO and are considered well within the purview of the prior art. Finally, it would have been obvious to one of ordinary skill in the art to use any known synthetic method to couple amides or amide equivalents with amines to form ureas or urea derivatives as such synthetic manipulations are considered well within the purview of the prior art. Similarly, acylating and sulphonylating are processes well known in the art and considered a choice of experimental design well within the purview of the prior art.

The applied reference, U.S. Patent No. 6,326,359 B1 to MONAGHAN et al., has a common inventor and/or assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be

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overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Conclusion

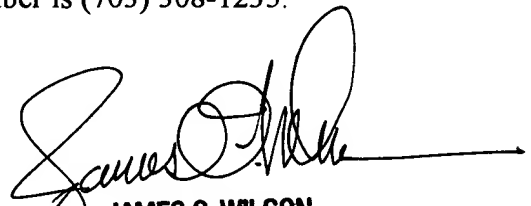
Claims 1-26, 43-46 and 48-54 are pending. Claims 1-26, 43-46 and 48-54 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Josephine Young whose telephone number is (703) 605-1201. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (703) 308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JY
May 29, 2003



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Interview Summary

Application N

09/884,244

Applicant(s)

MANTELL ET AL.

Examiner

Josephine Young

Art Unit

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All participants (applicant, applicant's representative, PTO personnel):

(1) Josephine Young.

(3) _____.

(2) Robert T. Ronau.

(4) _____.

Date of Interview: 28 May 2003.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.

If Yes, brief description: _____.

Claim(s) discussed: 1-26,43-46 and 48-54.

Identification of prior art discussed: US 6,326,359 to MONAGHAN et al..

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Examiner indicated possible allowable subject matter in the present application with the proviso that the claims need to be amended such that the non-enabled 5'-dialkyluronamide embodiment is cancelled and that a terminal disclaimer is timely filed.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent and Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.